

LOW CALORIC DENSITY ENTERAL FORMULATION DESIGNED TO REDUCE DIARRHEA IN TUBE-FED PATIENTS

BACKGROUND OF THE INVENTION

The present invention relates generally to the feeding of a patient, through a tube, with an enteral product. More specifically, the present invention relates to the prevention of diarrhea in a tube-fed patient.

It is known to feed patients, requiring nutrition in a hospital or other healthcare setting (including a home), with an enteral or parenteral nutritional solution. Parenteral nutritional solutions include solutions that are infused into the venous system of a patient through an IV system. Enteral products include products that are fed to a patient through a tube that is fed through the nasogastric system.

Although enteral products fed through a nasogastric tube can provide a patient with total nutritional requirements, there are, in certain patients, some side effects from such feedings. In this regard, it is known that certain patients will experience diarrhea when tube fed enteral nutritional products.

Diarrhea is cited as the most common cause of interrupted tube feeding. Likewise, diarrhea is cited as the most frequent complaint of tube-fed patients. Many hospital nurses, dietitians, and physicians have identified the reduction of diarrhea as being one of the most desirable areas of patient care. In this regard, diarrhea effects approximately 10 to 40% of the tube-fed hospitalized patients. It is also known, to a lesser extent that tube-fed patients experience nausea and abdominal distension.

To help to reduce the incidence of diarrhea, it is known to put fiber or other anti-diarrhea composition in enteral formulations. Due to problems with keeping a particulate substance in suspension, only a certain amount of fiber can be loaded in a typical enteral formulation. For example, typical fiber containing enteral products include 14 grams of insoluble soy polysaccharide (fiber) per liter and have a caloric density of 1.0 Kcal/ml.

The addition of insoluble fiber, however, does not eliminate the incidence of diarrhea. Therefore, it is common practice in U.S. hospitals, when faced with a tube-fed patient with diarrhea, to initially reduce the flow rate and/or concentration of the enteral product. It is expected that because fluid volume and osmolality are reduced, the diarrhea will also be reduced.

Accordingly, hospitals dilute such enteral products to three-quarter to one-half strength. This reduces nutrient load, theoretically reducing malabsorption, and also reduces osmolality. Although improvements should be expected when the fluid volume and osmolality of an enteral product are reduced, to achieve the reduced osmolality, the hospital merely dilutes the product. For example, the product is mixed with water so as to be diluted to 50%.

The disadvantage of this procedure is that the fiber, or other anti-diarrhea composition, in the enteral product is likewise reduced. Therefore, the dilution of the product does not always result in a reduction in the severity of the diarrhea. Furthermore, the dilution process can compromise the sterility of the enteral product. Still further, because the product is diluted, essential

vitamins and minerals are not supplied in adequate quantity.

SUMMARY OF THE INVENTION

The present invention provides an enteral nutritional product that can be used to tube feed a patient and reduce the incidence or severity of diarrhea. To this end, the present invention provides an enteral product that meets most of the daily nutritional requirements of hospitalized patients. However, the product has a sufficiently reduced caloric density and osmolality, but a sufficiently high fiber content, to reduce or eliminate the risk of diarrhea.

To this end, the present invention provides an enteral product for providing nutritional requirements to a patient comprising: a caloric content of less than 1.00 Kcal/ml; an osmolality of less than 300 mOsm; and a fiber content of at least 14 gms/liter and preferably greater than 15 gms/liter.

In an embodiment, the product includes approximately 18 to about 25% of the total calories as protein.

In an embodiment, the product includes approximately 35 to about 50% of the total calories as fat.

In an embodiment, the fiber includes one or more components chosen from the group consisting of: insoluble soy polysaccharide; insoluble pectin; hydrolyzed plant gums; carob pod; and tannin-enriched extract of carob pod.

Additionally, the present invention provides a method of providing nutrition to a patient through a tube-fed enteral product and reducing the risk of diarrhea comprising the steps of: providing a sterile enteral product, that does not require diluting, having an osmolality of less than 300 mOsm and a caloric content of less than 1.0 Kcal/ml but having a fiber content of greater than 15 gms/liter; and enterally administering the product to a patient.

An advantage of the present invention is that it provides a prediluted product with a high fiber content.

Furthermore, an advantage of the present invention is that it provides a sterile closed system that does not have to be diluted before use.

Still further, an advantage of the present invention is that it provides a product having a higher than typical protein content, as a percentage of calories, to help meet protein requirements in a calorie reduced product.

Moreover, an advantage of the present invention is that the composition has a vitamin and mineral composition which meets vitamin and mineral requirements in a calorie reduced product.

Additionally, an advantage of the present invention is that the composition has a higher lipid content that helps to reduce osmolality and slow transit time.

Additional features and advantages of the present invention are described in, and will be apparent from, the detailed description of the presently preferred embodiments.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENTS

The present invention provides an enteral product suitable for tube feeding that provides most of the daily nutritional requirements of hospitalized and nursing home patients. The product has a caloric density of less than 1.0 Kcal/liter. In a preferred embodiment, the present invention provides a product with a caloric density of approximately 0.5 to about 0.8 Kcal/ml.